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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,202	08/21/2003	Paul C. McAfee	04-005-US1	7244

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EXAMINER

SHAFFER, RICHARD R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/645,202	Applicant(s) MCAFEY, PAUL C.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9,10,12-14 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/21/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-6, 9-10, 12-14, and 18-24) in the reply filed on July 19th, 2006 is acknowledged.

Claims 7, 8, and 15-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 19th, 2006.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because they fail formal requirements (see attached Draftsperson's Drawing Review), do not clearly depict the invention, lack reference numerals, have text written on the Figure sheets, Figure sheets are not labeled such as 1/11, 2/11, etc, and are generally unprofessional. One of ordinary skill would be unduly challenged in understanding the current invention due to the drawings. Applicant is advised to employ

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the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The disclosure is objected to because on page 2, Line 4, applicant states "DYNESES (TM)" when it should be "DYNESYS (TM)." Further, Line 8, applicant states "Dynesys (TM)" when it should be "DYNESYS (TM)."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "further comprising an anchor to a bone, to which said sleeve" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. Applicant has already claimed 2 bone anchors, now reciting a third bone anchor. While this is supported, it is unclear which of the two sleeves previously claimed are in fact attached to a third bone anchor and thus not attached to the original two bone anchors. Claims 12 and 13 are rejected for being dependent upon an indefinite base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9-10, 12-14, 18-20, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner et al (EP 0 669 109 B1).

Baumgartner et al disclose a system comprising: at least pedicle screws (**2,3; Claim 1**); a longitudinal spinal rod (**1**); the rod disposed within two sleeves (**25 and 26**); the sleeves each having an internal surface made of polyurethane (**claim 6**) and an external surface (**7 and 15, Figures 2 and 3**); the spinal rod (**1**) is free to glide within the sleeves when not locked by setscrews (**8**); a bumper (middle section of **10/16/21**) between sleeves (**25, 26**); the bumper maintains a distance between the two sleeves; and the bumper is adjacent a sleeve during extension and has a gap (**24, 38**) during flexion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner et al.

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Baumgartner et al disclose all of the claimed limitations except for the inner sleeve layer being made of UHMWPE, the outer sleeve layer being made from one of stainless steel and alloys, cobalt and alloys, and titanium and alloys, and the use of cross-links. It is well known in the art to use transverse rod connectors / cross-links to stabilize parallel rods in relationship to one another. One having ordinary skill in the art at the time the invention was made would have readily utilized a cross-link in the device of Baumgartner et al, especially in instances where the rods extended over a prolonged distance of the spine.

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed materials since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. In the instant case, it would have been a mere selection of UHMWPE over polyurethane and a very well known metal for a pedicle screw.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
August 30th, 2006



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER